I. REMARKS

Preliminary Remarks

Claims 148 to 151, 175, and 177 to 191 are pending, of which claims 148, 175, and 179 are independent. No claims are added, withdrawn, amended, or canceled.

This response is filed within the shortened statutory period for response, no fee due, and is accompanied by abstracts of 15 scientific articles (9 pages). The applicants respectfully request reconsideration and allowance of the present application.

Patentability Remarks

Rejection under 35 U.S.C. §112 –

Claims 148 to 151, 175, and 177 to 191 were rejected under 35 U.S.C. §112, first paragraph, for scope of enablement. The applicants respectfully traverse.

The examiner's argument appears to be that the claims are broad, undue experimentation would be required, and the specification as filed contains no working examples. The examiner has, however, no basis for setting forth this rejection.

Lymphoproliferative disorders consists of conditions characterized by immune suppression (*e.g.*, excess of T-suppressor cells as in AIDS) and immune over-stimulation (*e.g.*, excess of T-helper cells as in the auto-immune and inflammatory disorders). The claimed method of treating autoimmune diseases comprising administering a composition of boswellic acids is an unexpected departure from conventional thinking about immune system disorders, yet based on published phenomenon of different directions in growth and proliferation of various lymphoid cells in different clinical conditions. Therefore the inventive concept is not a "hunting license" as disparagingly stated by the examiner, but a strikingly novel interpretation of solid experimental data.

Shao *et al.* (*Planta Med.* **64(4)**, 328 - 331, May 1998) showed for the first time advantages of a composition comprising a mixture of boswellic acids which inhibit RNA, DNA, protein and cell proliferation in the Human Leukemia cell line (HL-60) *in vitro*. Contrary to the examiner's contention, the specification as filed provides working

examples of this inhibition (pages 6 to 8). The depression of RNA, DNA, protein, and cell growth of HL-60 cells by various boswellic acids is indicative of cytostatic, immuno-suppressive and immuno-modulatory properties of the claimed composition. Despite the examiner statement on page 4 of the official action that "The skilled artisan would view that by administering the VERY same boswellic acids composition (for immunosuppression and immunopotentiation) is highly unpredictable", the invention meets the reality of clinical practice.

Specifically, the use of the same cytostatic drugs in diversified fields of medical treatments in cancer (*e.g.*, human leukemia), autoimmune disease (*e.g.*, rheumatoid arthritis), to control inflammation (*e.g.*, Uveitis condition) and to control CD4 cell in AIDS patients is actually practiced based on available literature. Treatment of a disease is an art and predictable outcome is based on a judgment of a physician. The applicants include the abstracts of several publication showing that the inhibition of RNA, DNA, protein, and cell growth of HL-60 cells by various boswellic acids is indicative of treatment of autoimmune diseases in general.

Indeed, the applicants respectfully remind the examiner that, according to current U.S. patent practice, they are not required to provide any experimental data and certainly need not provide any more than already in the specification as filed. The applicants also respectfully remind the examiner that the standard is undue experimentation, not merely experimentation. The applicants submit that one of ordinary skill in the art would not be required to conduct undue experimentation to practice the invention.

In conclusion, the applicants respectfully submit that the specification as filed fully enables claims 148 to 151, 175, and 177 to 191 per the requirements of 35 U.S.C. §112, first paragraph, and respectfully request withdrawal of this rejection.

Rejections under 35 U.S.C. §103 –

Claims 148 to 151, 175, and 177 to 191 were rejected under 35 U.S.C. §103(a) as being unpatentable over Koji *et al.* (JP 04-288095, also referred to by the examiner as Nagasawa *et al.*). The applicants respectfully traverse.

The examiner has merely repeated the comments made earlier without addressing the applicants rebuttal in any of their responses, including the Appeal Brief. This is contrary to the examination procedure that the U.S. Patent and Trademark Office requires the examiner to follow. "Where the applicant traverses any rejection, the examiner should, if he or she repeats the rejection, take note of the applicant's argument and answer the substance of it." (M.P.E.P. §707.07(f), emphasis added). The examiner's burden of answering the substance of a rejection is not discharged by merely repeating the words of the earlier rejection *verbatim*.

For the sake of brevity, the applicants do not repeat their arguments already filed and reiterated. The applicants incorporate their prior arguments with respect to Koji *et al.* in their entirety herein by reference. The applicants respectfully add that the formula of Koji *et al.* is different from the claimed invention because the methods of the claimed invention do not use α-hydroxy boswellic acids. Further the "complement activity inhibitor" mechanism of Koji *et al.* is different from the mechanism of the currently claimed invention. Therefore, Koji *et al.* do not fairly teach or suggest the claimed invention to one of ordinary skill in the art.

Therefore for at least the reasons previously and currently provided the applicants respectfully submit that claims 148 to 151, 175, and 177 to 191 are not unpatentable under 35 U.S.C. §103(a) over Koji *et al.* and respectfully request withdrawal of this rejection.

Claims 148 to 151, 175, and 177 to 191 were rejected under 35 U.S.C. §103(a) as being unpatentable over Taneja *et al.* (EP 0 755 940). The applicants respectfully traverse.

Once again, the examiner has not followed U.S. Patent and Trademark Office procedure for examination of the present application as embodied in, *inter alia*, M.P.E.P. §707.07(f). For the sake of brevity, the applicants do not repeat their arguments already filed and reiterated, which the applicants incorporate in their entirety herein by reference. The applicants respectfully submit that: (1) they have fully addressed and overcome the rejection over Taneja *et al.*, (2) the burden of rebutting the applicants' arguments has shifted to the examiner, and (3) that the examiner has not discharged

her burden by merely repeating the rejection without addressing its substance. Therefore, the applicants respectfully submit that claims 148 to 151, 175, and 177 to 191 are not unpatentable under 35 U.S.C. §103(a) over Taneja *et al.* and respectfully request withdrawal of this rejection.

II. CONCLUSION

In view of the remarks above, the applicants respectfully submit that this application is in condition for allowance and request favorable action thereon.

In the event this response is not timely filed, the applicants hereby petition for an appropriate extension of time. The fee for this extension, along with any additional fees required with respect to this response, may be charged to Deposit Account No. 01-2300, referencing Attorney Docket No. 108064-00049.

Respectfully submitted,

ARENT FOX PLLC

Gautam Prakash, Ph.D.
Registration No.: 53,481
Direct Telephone No.: 202-857-6057

Customer No.: **004372**

1050 Connecticut Avenue, N.W.
Washington, D.C. 20036-5339

Telephone No.: 202-857-6000
Facsimile No.: 202-857-6395

/GP